UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

FREE STATE OF BAVARIA, *represented by* THE UNIVERSITY OF WÜRZBURG Sanderring 2 97070 Würzburg, Germany Plaintiff, v. THE OHIO STATE UNIVERSITY, an Ohio public academic institution, 281 W. Lane Avenue Columbus, Ohio 43210 also serve: David Yost, Attorney General 30 E. Broad Street, 14th Floor Columbus, Ohio 43215 NATIONWIDE CHILDREN'S HOSPITAL, an Ohio not-for-profit corporation, 700 Children's Drive Columbus, Ohio 43205 also serve: Statutory Agent Rhonda L. Comer 700 Children's Drive 7th Floor-OCC Columbus, Ohio 43205 THE RESEARCH INSTITUTE AT NATIONWIDE CHILDREN'S HOSPITAL, an Ohio not-for-profit corporation, 700 Children's Drive Columbus, Ohio 43205 also serve: Statutory Agent Rhonda L. Comer 700 Children's Drive 7th Floor-OCC Columbus, Ohio 43205	CASE NO. JUDGE **COMPLAINT** **(Jury Trial Demanded)**

and

BRIAN KASPAR, M.D.,
17585 Ranchito Del Rio
Rancho Santa Fe, California 92067

Defendants.

NOW COMES Plaintiff Free State of Bavaria, represented by the University of Würzburg, and for its Complaint against Defendants The Ohio State University, Nationwide Children's Hospital, The Research Institute at Nationwide Children's Hospital, and Brian Kaspar, M.D. (collectively "Defendants"), alleges and states as follows:

INTRODUCTION

Spinal Muscular Atrophy ("SMA") is a horrific congenital disease, caused by a particular genetic defect, that is regularly fatal to children. Happily, using genetically modified mice created by Dr. Michael Sendtner ("Dr. Sendtner") at the University of Würzburg ("Würzburg"), a leading German research university with 14 Nobel laureates to its credit, a treatment for SMA was discovered and made available across the world. Defendants exploited Würzburg's invention to conduct commercial research that ultimately culminated in an $8.7 billion acquisition of the therapy by Novartis. That gene therapy is now among the most expensive in the world, retailing for over $2 million per dose. Although Defendants profited handsomely from this success, they never compensated Würzburg for its critical role in this medical innovation despite clear legal obligations to do so. Würzburg deeply regrets the need to resort to litigation to vindicate its rights, but, as a non-profit public institution and agent of the Free State of Bavaria, it has a fiduciary duty to do so. Thus, Würzburg is pursing breach of contract, breach

of fiduciary duty, fraud, rescission, unjust enrichment, tortious interference with a contract, civil conspiracy, and declaratory judgment claims against Defendants in this Court.

PARTIES

1. Plaintiff Free State of Bavaria is a state in the south-east of Germany. The University of Würzburg ("Würzburg") is a public German university with a principal address of Sanderring 2, 97070 Würzburg, Germany. Würzburg acts as the agent of the Free State of Bavaria with respect to all work product, inventions, and intellectual property created by Würzburg personnel and discharges its individual legal authority to exploit these assets for commercial use and to assert rights relating to those assets.

2. Defendant The Ohio State University ("OSU") is a public academic institution organized under the laws of the State of Ohio with a principal address of 281 W. Lane Avenue, Columbus, Ohio 43210, in this District.

3. Defendant Nationwide Children's Hospital ("NCH") is a not-for-profit corporation organized under the laws of the State of Ohio with its principal place of business at 700 Children's Drive, Columbus, Ohio 43205, in this District.

4. Defendant The Research Institute at Nationwide Children's Hospital ("The Research Institute") is a not-for-profit corporation organized under the laws of the State of Ohio with its principal place of business at 700 Children's Drive, Columbus, Ohio 43205, in this District.

5. Defendant Brian Kaspar, M.D. ("Kaspar") is a doctor, medical researcher, and resident of the state of California, with an address of 17585 Ranchito Del Rio, Rancho Santa Fe, California 92067. During the relevant period, Kaspar was also a resident of Ohio, an employee of NCH, and a Professor of Pediatrics at The Research Institute.

JURISDICTION AND VENUE

6. The parties are diverse and the amount in controversy is greater than $75,000, giving this Court subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

7. This Court has personal jurisdiction over OSU,[1] NCH, and The Research Institute because they are organized under the laws of Ohio, have principal places of business in this District, intentionally avail themselves of the rights and privileges of conducting business in Ohio, have continuous and systematic contacts with Ohio, and have caused injury in Ohio as a direct result of Defendants' conduct in that state.

8. This Court has personal jurisdiction through Ohio's long arm statute over Kaspar because the causes of action stated herein arise from Kaspar's transaction of business in Ohio, including his ongoing employment in the State, and the tortious injury caused by his acts and omissions in Ohio.

9. Personal jurisdiction over Kaspar comports with Kaspar's constitutional right to due process because he had, and continues to have, minimum contacts with Ohio as demonstrated by the fact that he 1) purposefully availed himself of the privilege of acting in Ohio, 2) the causes of action described herein arises from Kaspar's activities in Ohio, and 3) Kaspar's acts and the consequences caused by Kaspar's acts have a substantial connection with Ohio such to make the exercise of jurisdiction over Kaspar compatible with due process.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims herein occurred in this

[1] Würzburg has also filed a complaint alleging the same causes of action against OSU in the State of Ohio Court of Claims. If OSU waives its rights under the Eleventh Amendment, then this case can go forward against all parties in this Court, which would be more efficient for the courts and the parties. Otherwise, the case against OSU will proceed in the Court of Claims while the case against NCH, The Research Institute, and Kaspar will continue in this Court.

judicial district and because Defendants regularly conduct business in this judicial district. Venue is also proper in this Court pursuant to 28 U.S.C. § 1391(b)(1) because OSU, NCH, and The Research Institute have principal places of business in this District.

NATURE OF THE COMPLAINT

11. This is an action by Würzburg for breach of contract, breach of fiduciary duty, fraud, unjust enrichment, recission, declaratory judgment, tortious interference, and civil conspiracy.

12. This case arises from the unauthorized use of Würzburg's genetically modified mice—mice that were the launching pad for Defendants' commercial gain.

13. Research conducted by Dr. Sendtner, a Professor of Clinical Neurobiology at Würzburg, resulted in the creation of mice that have a deleted SMN1 gene, the same gene missing in humans who have SMA (hereafter, all mice containing this genetic modification will be referred to as "mice containing Dr. Sendtner's knockout allele"). These mice were crucial to the discovery of a therapeutic agent to treat SMA, which works by inserting the missing SMN1 gene. Despite its contribution and contractual entitlements to compensation, Würzburg has received nothing for the unauthorized use of mice containing this genetic modification.

14. In the late 1990s and early 2000s, because it realized the importance of Dr. Sendtner's invention, Würzburg agreed to the transfer of the mice containing Dr. Sendtner's knockout allele to other institutions. To that end, in 2002, Würzburg agreed to allow OSU to crossbreed Dr. Sendtner's mice containing the SMN knockout allele with other genetically-modified mice from the lab of Dr. Arthur Burghes at OSU. The combination created a mouse model that mimicked SMA in humans and would permit researchers to conduct studies of future therapies.

15. OSU and Würzburg reached an agreement that governed the distribution and use of the mice containing both Dr. Sendtner's knockout allele and Dr. Burghes' genetic contribution, and defined what compensation Würzburg would receive if its invention was used for commercial purposes (the "Agency Agreement," attached at Exhibit 1[2]).

16. Under the Agency Agreement, OSU agreed to act as Würzburg's agent for the purposes of licensing and transferring mice containing Dr. Sendtner's knockout allele. OSU agreed that if any entity requested the mice, OSU would provide that entity with Würzburg's standard Material Transfer Agreement ("MTA") as a precondition to transferring the mice to the requesting entity. OSU further agreed that no mice would be transferred to any requester until Würzburg's MTA was executed by both Würzburg and the requesting entity.

17. MTAs are regularly used in academia to facilitate the transfer of tangible materials, like assays, cells lines, and mouse strains, for research purposes. MTAs define the rights of the providing institution as well as the obligations of the recipient regarding the materials. In so doing, these agreements spur collaboration across institutions and geography and facilitate the free exchange of information and technology.

18. Würzburg's MTA enabled other institutions to freely use the mice and derivatives for academic and research purposes, subject to the requirement that Würzburg would receive 10% of profits from any commercialization achieved as a result of using the mice ("the 10% of Profits Clause").

19. As a supplement to the Agency Agreement, OSU and Würzburg also agreed that OSU could freely conduct research on these mice, but if OSU ever commercialized any

[2] The Agency Agreement is comprised of multiple communications between the parties. Attached as Exhibit 1 are some of the documents that constitute the Agency Agreement.

invention as a result of such research, it would also execute Würzburg's MTA and be subject to the 10% of Profits Clause.

20. In violation of the Agency Agreement, around 2004, OSU transferred mice containing Dr. Sendtner's knockout allele to Kaspar at Nationwide Children's Hospital ("NCH") and The Research Institute at NCH, without obtaining a signed MTA.

21. Upon information and belief, when transferring these mice, OSU protected its own rights through the execution of its own, separate MTA with Kaspar, The Research Institute, and/or NCH, while wholly ignoring and prejudicing Würzburg's contractual and property rights in the very same mice.

22. Kaspar, NCH, and The Research Institute never executed an MTA with Würzburg. OSU, NCH, The Research Institute, and Kaspar each conducted research and experiments using mice containing Dr. Sendtner's knockout allele without Würzburg's consent, knowledge, or authorization.

23. Said experimentation led to the discovery of a commercial drug product—which worked by inserting the missing SMN1 gene into the human genome—and the formation of AveXis, an OSU incubator whose primary purpose was to commercialize this gene therapy to treat SMA. OSU never executed Würzburg's MTA, nor did it ever notify Würzburg of its plans to commercialize the potential therapeutic for profit.

24. OSU worked with AveXis and The Research Institute at NCH to develop the therapeutic for SMA and conducted pre-clinical trials. OSU's incubator, AveXis, was acquired by Novartis in 2018 for $8.7 billion. The U.S. Food and Drug Administration ("FDA") ultimately approved the gene therapy in May 2019, and Novartis began selling the therapy in June 2019.

25. As these developments transpired, Würzburg was left in the dark. The most OSU did was approach Würzburg in late 2016, to request an Inter-Institutional Agreement ("IIA") with respect to mice containing Dr. Sendtner's knockout allele. But rather than tell Würzburg about developments involving the mice over the past several years, OSU claimed it had "just" discovered that Würzburg was a partial owner of the mice.

26. OSU did not disclose that AveXis, Kaspar, NCH, and The Research Institute had already been using mice containing Dr. Sendtner's knockout allele to develop a drug product for the treatment of SMA. Nor did OSU disclose that the drug product was being used in clinical studies with the intent to apply for FDA approval. Most importantly, OSU did not inform Würzburg about its own past and future plans to license their shared technology, the ongoing clinical studies involving mice containing Dr. Sendtner's knockout allele, and that an acquisition of AveXis was potentially in the works.

27. As a result of OSU's omissions and misrepresentations, Würzburg signed the IIA on September 25, 2017. That agreement permitted the two institutions to license mice containing Dr. Sendtner's knockout allele in exchange for a licensing fee of $80,000 to be shared between Würzburg, OSU, and Jackson Laboratories ("Jackson Labs"), a biomedical research institution that acts as a central repository for thousands of strains of genetically modified mice.

28. OSU insisted, without divulging critical facts, that the IIA take effect and be back-dated to 2005. OSU agreed in the IIA to pay Würzburg a paltry $25,000 as compensation for the period of April 14, 2005 until July 1, 2017. Würzburg agreed to this amount, because it believed that OSU had only received approximately $100,000 from prior licensing.

29. With the ink barely dry on the parties' 2017 agreement, in May 2018, Novartis acquired AveXis for a record $8.7 billion. Each share of AveXis common stock was converted to $218.00 per share. OSU, NCH, and Kaspar all owned shares of AveXis stock.

30. In June 2019, the FDA approved a New Drug Application for Zolgensma (onasemnogene abeparvovec), the drug product developed using mice containing Dr. Sendtner's knockout allele, which AveXis developed.

31. Today, Novartis sells Zolgensma at a list price of $2.125 million per injection.

32. The sales of Zolgensma are approximately $1 billion each year.

33. Based on the commercialization of mice containing Dr. Sendtner's knockout allele, OSU, NCH, and The Research Institute together received, at a minimum, 3% ownership of AveXis, as well as royalties going forward for the sales of Zolgensma.

34. As a result of the commercialization of mice containing Dr. Sendtner's knockout allele and as evidenced by SEC filings, Kaspar received more than $380 million from AveXis's 2018 acquisition by Novartis.

35. Neither Dr. Sendtner nor Würzburg has received any revenue from the commercialization of mice containing Sendtner's knockout allele, despite the explicit agreement between OSU and Würzburg to the contrary. The parties clearly agreed that execution of Würzburg's MTA was a prerequisite to the transfer of any mice containing Sendtner's knockout allele. The parties also agreed that OSU would likewise execute Würzburg's MTA if OSU intended to use the mice for commercial purposes.

36. Having skirted Würzburg's MTA requirements, Defendants OSU, NCH, The Research Institute, and Kaspar meanwhile profited from Würzburg's invention, without ever compensating Würzburg, and have been unjustly enriched.

37. As a result of Defendants' breaches and other actions, Würzburg has suffered direct financial damages and continues to incur additional damages.

FACTS RELEVANT TO ALL COUNTS

a. Spinal Muscular Atrophy

38. SMA is a genetic disorder that affects the central nervous system, peripheral nervous system, and skeletal muscles, and leads to the deterioration of various physical functions. The disease impedes the function of motor neurons by reducing the survival motor neuron protein ("SMN protein") found in the motor neurons of the spinal cord. Motor neurons control muscle movement, so SMA patients are unable to use their muscles, and their muscles weaken and eventually waste away. Ultimately, SMA patients are unable to move or even breathe. Infants born with SMA generally do not survive past their second birthdays, and the disease also has devastating effects on adults.

39. Humans have two so-called "survival motor neuron" genes ("SMN genes," which are the specific portions of DNA that makes the SMN protein), called SMN1 and SMN2. In patients with SMA, the SMN1 gene is missing or altered, so that SMN protein cannot be made. In these individuals, the SMN2 gene intervenes to a certain extent, but is not able to fully compensate for the loss of the SMN1 gene function, as SMN2 does not make nearly as much SMN protein as SMN1.

40. After the SMN genes were identified and mapped by researchers, a critical step in developing potential therapeutic agents to treat SMA was the development of an animal model of SMA to test those agents, including attempting to insert the missing gene back into the animal's genome (known as gene therapy). Mice are commonly used for such experimentation. However, unlike humans, mice have only one SMN gene, the SMN1 gene. Therefore, to create a

mouse model of SMA, the mouse SMN gene would need to be removed, or "knocked out" entirely from the mouse genome, and a human SMN2 gene would have to be inserted into the same mouse's genome.

b. Würzburg's critical medical innovation

41. In the late 1990s, Dr. Sendtner at the University of Würzburg finally succeeded in removing the SMN gene from the genome of mice and bred mice that had allele pairs of this trait. The SMN knockout mouse, or a mouse missing the SMN1 gene—the same gene that when missing in people causes SMA—was created.

42. Dr. Sendtner published the creation of his knockout mouse in the National Academy of Sciences of the United States of America in 1998, in an article entitled "Inactivation of the survival motor neuron gene, a candidate gene for human spinal muscular atrophy, leads to massive cell death in early mouse embryos." Dr. Sendtner was and continues to be an active contributor in the field of gene therapies.

43. In 1997, shortly after Dr. Sendtner published his article, he was contacted by Dr. Arthur Burghes from OSU, who was also conducting research on mice to better understand SMA.

c. Würzburg and OSU's collaboration

44. Between 1997 and 2002, Drs. Burghes and Sendtner communicated regularly, including at Spinal Muscular Atrophy Foundation events in the United States and abroad. During this time, Drs. Burghes and Sendtner extensively discussed Dr. Sendtner's research on gene therapy and the need for novel viral vectors—a tool for delivering genetic material into cells—to allow for the continuous delivery of drugs and therapeutic gene expression.

45. While at OSU, Dr. Burghes genetically modified mice by implanting the human SMN2 gene into the genome of the mice. Drs. Burghes and Sendtner recognized that the breeding of Dr. Sendtner's mice that were heterozygous for the missing SMN gene with Dr. Burghes' SMN2 mice would result in the long sought-after mouse model of SMA.

46. In the late 1990s, Dr. Sendtner sent his mice to OSU where they were cross-bred with Dr. Burghes' mice to create the SMN-/SMN2 hybrid mice—mice containing the SMN "knockout allele" discovered by Dr. Sendtner and the human SMN2 gene from Dr. Burghes. To confirm that genetic profile, the hybrid mouse carcasses were sent to Dr. Sendtner for analysis. Dr. Sendtner confirmed that the hybrid mice, which included the SMN knockout allele, had the biological and genetic traits to make them a successful and accurate animal model of SMA. This discovery represented a major leap in the development of a cure for SMA.

47. Drs. Sendtner and Burghes also found that even installing two copies of the SMN2 gene into the hybrid mouse genome could not compensate for a missing SMN1 gene, but that eight SMN2 genes gave complete rescue of the hybrid mice. The SMA mice were published in *Human Molecular Genetics*, an important industry publication, and presented at academic conferences around the globe.

48. Dr. Sendtner, along with Würzburg's administration, wanted to allow other institutions and companies to use the hybrid mouse containing Dr. Sendtner's knockout allele with the hopes that a treatment for SMA could be developed. They decided to permit other institutions to use the mice under the condition that Würzburg would receive 10% of any profit from the commercial use of the mice containing Dr. Sendtner's knockout allele.

d. OSU agrees to act as the University of Würzburg's agent

49. By 2002, the scientific community recognized the potential of the mice containing Dr. Sendtner's knockout allele as a tool for discovering a cure for SMA. Indeed, OSU, where the mice were being bred, began receiving inquiries from both academic and commercial institutions about these mice.

50. Because of the demand for the SMN-/SMN2 mice, and because Würzburg and OSU jointly owned and created the mice, OSU specifically agreed to act as Würzburg's agent for the licensing and transfer of the mice. In the Agency Agreement, OSU specifically committed not to distribute any mice containing Dr. Sendtner's knockout allele to any entity without first providing that entity with Würzburg's MTA. In addition to ensuring execution of Würzburg's MTA, OSU also provided these third-parties with its own MTA, covering its part of the mouse.

51. While OSU was permitted to conduct research on the mice containing Dr. Sendtner's knockout allele, Würzburg and OSU agreed that, as required by Würzburg's governing grants and local laws if OSU itself ever sought to commercialize a drug product using these mice, it too would need to execute Würzburg's MTA.

52. OSU accepted its obligations as Würzburg's agent and repeatedly assured Würzburg that it would not transfer mice without Würzburg's authorization. OSU's Dr. Burghes, for example, sent Dr. Sendtner a list of requesting entities that sought the mice containing Dr. Sendtner's knockout allele, stating that, "I have informed them that they must get permission from you before I can send them unless they just want the SMN2 gene." [July 23, 2002 email from Burghes to Sendtner, at Ex. 1; July 29, 2002 German email from Sendtner to Loeffler, at Ex. 1 (relaying that OSU agreed to become a partner in having Würzburg's MTA signed).]

53. Initially, OSU's Dr. Burghes would inform Dr. Sendtner each time an institution requested the mice and ask for Würzburg's MTA. OSU at all times recognized that the mice that had been crossbred with Würzburg's mice were subject to the MTA protocol. On August 27, 2002, for example, Dr. Burghes informed a requesting institution that "to ship the mice to you would also require an MTA with Michael Sendtner in Germany as his group derived the knockout allele." [August 27, 2002 email from Burghes to Lin, at Ex. 1.] Dr. Burghes then told Dr. Sendtner that OSU had also provided the requester with OSU's own MTA for the SMN2 transgene. [August 28, 2002 email from Burghes to Sendtner, at Ex. 1.]

54. To streamline future transfers, Dr. Sendtner instructed Dr. Burghes to "keep the MTA" and "send it directly to persons who would like to have [the hybrid mice]." [August 28, 2002 email from Sendtner to Burghes, at Ex. 1.] This procedure simply eliminated the initial step of introducing the requesting institution to Dr. Sendtner. Requesting institutions now received the MTA from OSU, executed the MTA, and submitted the MTA for Würzburg's countersignature.

55. The procedure worked seamlessly—or so Würzburg thought at the time. On October 16, 2002, University of Florida researcher Kevin Foust ("Foust") was directed to Dr. Sendtner by Dr. Burghes about obtaining mice. [August 16, 2002 email from Foust to Sendtner, attached as Exhibit 2.] Foust was provided the Würzburg MTA and provided it to the appropriate office at his institution. [August 23, 2002 email from Foust to Sendtner, attached as Exhibit 3.]. On October 28, 2002, the University of Florida executed Würzburg's MTA. [*See* the MTA with the University of Florida, attached as Exhibit 4.] Then, Foust followed up with Dr. Sendtner by email to confirm that Würzburg had in fact received the signed agreement and authorized OSU to send the hybrid mice containing Dr. Sendtner's knockout allele to the

University of Florida. [Oct. 25, 2002 email from Foust to Sendtner, attached as Exhibit 5.] Würzburg countersigned the MTA on November 5, 2002. [Ex. 4.]

56. On November 11, 2002, to further formalize the MTA procedure, Dr. Sendtner provided the OSU Office for Licensing Technology with a copy of Würzburg's MTA. Dr. Sendtner again instructed OSU to provide the MTA to anyone requesting the hybrid mice containing Dr. Sendtner's knockout allele from OSU. [November 11, 2002 email from Sendtner to Garber, at Ex. 1.]

57. On November 13, 2002, Kathleen Garber, an attorney from the OSU Office for Licensing Technology, responded to Dr. Sendtner's email and confirmed that OSU would only transfer such mice after Würzburg's MTA had been signed by the requesting entity. [November 13, 2002 email Garber to Sendtner, at Ex. 1.]

58. On November 22, 2022, OSU confirmed again that it was separately requiring the execution of its own MTA to authorize use of the OSU portion of the mice. [November 22, 2002 email from Garber to Sendtner, at Ex. 1.]

59. The MTA that Würzburg provided to OSU for all future transfers contained the 10% of Profits Clause, stating that the recipient must notify Würzburg if any profit is made by the commercial use of any inventions made through use of its "Material," which included those mice containing Dr. Sendtner's knockout allele, and that Würzburg would receive 10% of such profit. [Würzburg MTA, attached as Exhibit 6.] The MTA also provided for an additional $50,000 penalty for a failure to notify Würzburg. The exact provisions from the MTA are provided below:

> The RECIPIENT shall notify the PROVIDER if any profit is made by the COMMERCIAL USE of the inventions (either patented or not) made through the use of the MATERIAL. The PROVIDER shall receive 10% of such profit.

> If the RECIPIENT fails to notify the PROVIDER of filing a patent application or of making profit by COMMERCIAL USE as specified above, the PROVIDER shall receive the additional amount of 50,000 USD as penalty. [*Id*. at § II(7).]

60. The MTA defined "Commercial Use" as:

> The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a profit-orientated organization. COMMERCIAL USE shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a profit-orientated organization. However, industrially sponsored academic research shall not be considered a COMMERCIAL USE of the MATERIAL or MODIFICATIONS per se, unless any of the above conditions of this definition are met. [*Id*. at § I(10).]

61. The MTA defined "Material" as "Original Material, Progeny, and Unmodified Derivatives," but not including "modifications or other substances created by the recipient through the use of the material, which are not modifications, progeny or unmodified derivatives." [*Id*. at § I(6).]

62. The MTA defined "Original Material" as "Smn mutant mice or cells, cell lines, DNA, RNA or proteins derived from these mice." [*Id*. at § III(A).]

63. The MTA defined "Progeny" as "unmodified descendant from the Material, such as micro-organism from microorganism and/or recombinant DNA from recombinant DNA. PROGENY shall also include mouse lines which have been derived from a genetically modified mouse line by crossbreeding; or DNA, RNA, or proteins derived from mouse mutants and/or primary cells and cell lines derived from genetically modified mice or their descents." [*Id*. at § I(7).]

64. The MTA defined "Unmodified Derivatives" as "Substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Original Material," with examples including "cloned/subcloned Original Material, purified or fractionated subsets of the Original Material, and proteins expressed from DNA/RNA supplied by the Provider." [*Id*. at § I(8).]

65. The MTA defined "Modifications" as substances created by the Recipient which contain/incorporate the Material. [*Id*. at § I(9).]

66. Würzburg, OSU, and Dr. Burghes understood and agreed that the MTA entitled Würzburg to 10% of any profits derived from the "sale, lease, license, or other transfer of the 'original material, progeny, and unmodified derivatives' ('Material') or 'substances created by the recipient which contain/incorporate the material' ('Modifications') to profit-orientated organizations" including the "uses of the Material or Modifications by any organization, including Recipient, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Material or Modifications to a profit-orientated organization" ("Commercial Use") as a result of Dr. Sendtner's "Smn mutant mice or cells, cell lines, DNA, RNA or proteins derived from these mice" ("Original Material") or through the use of "progeny and unmodified derivatives" of such original material ("Material"). [*Id*.]

67. Würzburg and OSU understood and agreed that the transfer of any mice containing Dr. Sendtner's knockout allele could take place only after the MTA was signed.

68. Würzburg and OSU entered into the Agency Agreement, whereby OSU agreed to act as Würzburg's agent for the purpose of licensing the use of Dr. Sendtner's technology—the SMN knockout allele—and to ensure that Würzburg received 10% of any profit made by the

commercial use of any inventions resulting from mice containing the SMN knockout allele. OSU also benefited from this arrangement because as Würzburg's agent, it too would be permitted to license the use of mice containing the SMN knockout allele.

e. Würzburg facilitates use of its mice, subject to profit-sharing in future commercialization

69. Through the Agency Agreement, Würzburg held OSU out to the public as having authority to entertain requests for the mice containing Dr. Sendtner's knockout allele, provide its MTA containing the 10% of Profits Clause, and ensure that the MTA was executed before providing any requester with mice. Any entity requesting these mice would similarly know of OSU's authority to license the use of mice containing Dr. Sendtner's knockout allele on Würzburg's behalf and have reason to believe that OSU had the necessary authority to do so.

70. Foust of the University of Florida clearly understood that OSU had the authority to license and provide mice containing Dr. Sendtner's knockout allele. [October 25, 2002 email from Foust to Sendtner, at. Ex. 5 ("I have been informed by our licensing department that the sma mouse MTA has been completed and returned to your institution. Could you please confirm that you have received it? If so, I will make arrangements with Dr. Burghes for transport of the mice.").]

71. Würzburg received several signed MTAs from third-parties in furtherance of the Agency Agreement, including from the University of Florida. All institutions agreed to the terms of the MTA, including the 10% of Profits Clause, before receiving mice containing Dr. Sendtner's knockout allele from OSU.

72. In the hopes of advancing further medical research, Würzburg also separately agreed to transfer mice containing Dr. Sendtner's knockout allele to other institutions that both sought to conduct academic research and ultimately create a viable therapy for those afflicted

with SMA. In 2004, the Spinal Muscular Atrophy Foundation, a consortium of medical researchers and parents whose children suffer from SMA, approached Dr. Sendtner and expressed frustration about the slow progress towards a cure for SMA.

73. The Spinal Muscular Atrophy Foundation, aware of the 10% of Profits Clause in Würzburg's MTA, asked Würzburg to reduce the amount in exchange for funding for Dr. Sendtner's research. Dr. Sendtner and Würzburg agreed, and around 2004, Würzburg entered "the License Agreement" [Exhibit 7] and "the Sponsored Research Agreement" [Exhibit 8] with the Spinal Muscular Atrophy Foundation. These agreements allowed the Spinal Muscular Atrophy Foundation access to mice containing Dr. Sendtner's knockout allele through the distributor Jackson Labs.

f. OSU's unauthorized transfers to third-party institutions and early commercialization plans

74. Independent of Würzburg, Dr. Burghes continued to work with the hybrid mice at OSU. OSU's academic research did not require a Würzburg MTA unless and until there was a plan to commercialize the research.

75. With the help of other researchers, around 2003, an additional genetic modification was made at OSU to the mice containing Dr. Sendtner's knockout allele. A second expression of the delta 7 transgene was inserted into the mouse genome, which allowed the mice to live longer and made them better test subjects. Thus, the resulting SMN-/SMN2/SMNDelta7 mice contained Dr. Sendtner's SMN knockout allele, Dr. Burghes' SMN2 insertion, and the second expression of the delta 7 transgene (and therefore, still "mice containing Dr. Sendtner's knockout allele").

76. OSU then transferred these SMN-/SMN2/SMNDelta7 mice containing Dr. Sendtner's knockout allele to Kaspar, Professor of Pediatrics at The Research Institute at

Nationwide Children's Hospital. [*See* Grace Frank, *Zolgensma's Journey from Lab Idea to Gene Therapy for SMA*, SMA News Today (May 27, 2019), attached as Exhibit 9 (Kaspar explaining that he received the mouse model from "a colleague of mine at The Ohio State University, Dr. Arthur Burghes … we had connections right next-door, literally.").] But OSU never provided NCH or Kaspar with Würzburg's MTA, contrary to the terms of the Agency Agreement.

77. OSU never informed Würzburg or Dr. Sendtner that it sent mice containing Dr. Sendtner's knockout allele to The Research Institute, NCH, or Kaspar.

78. Upon information and belief, OSU had the other Defendants sign OSU's own MTA prior to the transfer of the SMN-/SMN2/SMNDelta7 mice containing Dr. Sendtner's knockout allele.

79. Upon information and belief, the primary researchers at NCH and The Research Institute who received the mice from OSU—Foust and Kaspar—knew that Würzburg and OSU had developed a cross-bred mouse. They also knew of and disregarded Würzburg's MTA requirement.

80. Foust, while at the University of Florida in 2002, requested and received the knockout mouse from OSU, pursuant to an MTA with Würzburg. Foust joined NCH in 2007 and proceeded to use the SMN/SM2/SMNDelta7 mice containing Dr. Sendtner's knockout allele to conduct further research on motor neurons. Foust never sought authorization from Würzburg to conduct research on the mice while at NCH.[3]

81. Kaspar, another lead researcher at NCH, also knew of Dr. Sendtner's contribution to the mouse model and disregarded Würzburg's MTA requirements. Around 2004, while at a neuroscience conference, Dr. Sendtner informed Kaspar that mice containing Dr. Sendtner's

[3] Würzburg's MTAs are institution-specific agreements. As such, the earlier MTA authorization granted to the University of Florida did not authorize the use of Würzburg's mouse lines at any other institutions.

knockout allele were available for transfer pursuant to the terms of Würzburg's MTA and the 10% of Profits Clause. Kaspar represented that he was using a mouse model in his research that did not contain Dr. Sendtner's knockout allele.

82. Dr. Burghes and collaborators published the SMN-/SMN2/SMNDelta7 mice containing Dr. Sendtner's knockout allele in *Human Molecular Genetics* in a March 2005 paper entitled "SMNDelta7, the major product of the centromeric survival motor neuron (SMN2) gene, extends survival in mice with spinal muscular atrophy and associates with full-length SMN."

83. Around this time, OSU also offered the SMN-/SMN2/SMNDelta7 mouse containing Dr. Sendtner's knockout allele for licensing without informing Würzburg. On April 14, 2005, OSU entered into an Agreement for Distribution with Jackson Labs for the purposes of facilitating distribution of mice within the biomedical community. [*See* Letter of Agreement for Distribution, attached as Exhibit 10.] The agreement allowed Jackson Labs to distribute three separate strains of mice, all of which included the SMN deletion contributed by Dr. Sendtner. Jackson Labs could not distribute the mice until the requesting party entered into a license agreement with OSU and the requester paid a license fee. Under the agreement, OSU would compensate Jackson Labs with 10% of any income that OSU received from licensing the mice, due within 60 days of receipt by OSU of such license revenue.

84. Upon information and belief, the agreement between Jackson Labs and OSU did not address Würzburg's portion of the mouse model and ignored Würzburg's MTA requirement. OSU did not inform Würzburg of this arrangement.

85. From 2005 on, Kaspar and Foust at The Research Institute and NCH, and Dr. Burghes at OSU, continued to conduct research on SMN-/SMN2/SMNDelta7 mice containing Dr. Sendtner's knockout allele to identify an effective treatment for SMA.

86. Unbeknownst to Würzburg, in 2010, Kaspar helped found AveXis, an incubator associated with OSU and NCH. AveXis was a self-described "clinical-stage gene therapy company dedicated to developing and commercializing" novel treatments for patients with rare neurological genetic disorders. Dr. Burghes served on the Scientific Advisory Board of AveXis.

87. On February 6, 2013, The Research Institute entered into an Inter-Institutional Agreement with OSU, under which OSU granted certain license rights in the technology it had developed to The Research Institute

88. In 2013, The Research Institute submitted an Investigational New Drug Application ("IND") for onasemnogene abeparvovec—the drug developed by Kaspar, the Research Institute, NCH, OSU, and AveXis, to treat SMA using mice containing Sendtner's knockout allele.

89. Approval of this IND would allow AveXis to start human clinical trials.

90. In September 2013, FDA approved the IND.

91. In October 2013, The Research Institute and NCH licensed their intellectual property and research derived from mice containing Dr. Sendtner's knockout allele to AveXis.

92. Also in 2013, OSU licensed its research and intellectual property derived from mice containing Dr. Sendtner's knockout allele to AveXis.

93. In exchange for the license, AveXis issued NCH and OSU 331,053 shares of common stock, plus additional shares over time such that their aggregate ownership would represent 3% of AveXis.

94. OSU and The Research Institute were also granted royalties from the future sales of any NCH-licensed commercial product.

95. In October 2013, Kaspar became the Chief Scientific Officer of AveXis.

96. Around 2015, the sponsor of the IND was transferred from The Research Institute to AveXis.

97. Around 2015, clinical trials of onasemnogene abeparvovec began at NCH.

98. In February 2016, AveXis announced prices of an Initial Public Offering.

99. In 2016, Foust became Director of Research and Development at AveXis.

100. OSU never indicated to Würzburg that: (1) it, NCH, and The Research Institute continued to use and conduct research on mice containing Dr. Sendtner's knockout allele; (2) it, NCH, and The Research Institute were developing a drug product for the treatment for SMA; and (3) pre-clinical drug trials were under way. OSU also never executed Würzburg's MTA, nor did it ever ensure that NCH or The Research Institute executed the MTA.

g. OSU conceals unauthorized transfers and material facts and induces Würzburg into a new agreement

101. As research and testing on a treatment for SMA progressed, and likely realizing that a profit windfall was on the horizon, OSU approached Würzburg to discuss the mice containing Dr. Sendtner's knockout allele. OSU claimed it had only *just* discovered Würzburg's involvement in the creation of the mice, and reiterated that companies were interested in licensing their shared mice. OSU, however, never informed Würzburg of its past breaches of the Agency Agreement, and never shared the material information about AveXis's clinical trials and potential future windfall.

102. OSU's initial overtures to Würzburg began in late 2016, when the Technology Commercialization Office at OSU emailed Würzburg's legal counsel to notify Würzburg that OSU had "recently discovered that Ohio State and Wuerzburg are joint owners of the SMNΔ7 mouse." Given this joint ownership, OSU sought an agreement that would authorize OSU to license the mice containing Dr. Sendtner's knockout allele. OSU attached "OSU's standard IIA

template" and encouraged Würzburg to sign. [December 13, 2016 email from Richards to Demling, attached as Exhibit 11.]

103. When Würzburg did not immediately sign OSU's IIA, OSU followed up in January 2017 with Würzburg's Technology Transfer Office. OSU claimed that it had received "another inquiry from a company that would like to license this mouse model" and represented this recent inquiry as the reason why it now needed a licensing agreement. OSU proposed an equal split of the $80,000 license fee with Würzburg. [January 23, 2017 email from Mess to Zwirner-Baier, at Ex. 11.]

104. To further encourage Würzburg to sign the IIA, Dr. Burghes later emailed Dr. Sendtner directly "about the Delta 7 mice which have the deletion allele that you made in them." He explained that "a series of companies were asking OSU for a license to use these mice" and that the "Wurzburg part of the mice also needs to be covered." He urged Dr. Sendtner to get Würzburg to respond and execute the IIA. [March 9, 2017 email from Burghes to Sendtner, attached as Exhibit 12.]

105. Dr. Sendtner suspected that Würzburg had not received any license fees from past mice transfers from Jackson Labs under the Spinal Muscular Atrophy Foundation license. Upon inquiring about this, he stated that he "learned that Ohio University has made over $100,000 in the last few years [from] income license fees, that is, funds to which we would be entitled as well." [April 27, 2017 email from Sendter to Zwirner-Bayer, at Ex. 12.]

106. In July 2017, OSU represented to Würzburg that more companies were requesting a license from OSU and again sought Würzburg's signature on the IIA. OSU again claimed that "we just discovered that Wuerzburg may have certain rights in this mouse strain so I have made the effective date of the IIA [April 14, 2005] the date that Ohio State first deposited this mouse

with the Jackson Laboratory." [July 6, 2018 email from Mess to Zwirner-Bayer, attached as Exhibit 13.] OSU claimed that it was "in the process of responding to 2 companies that have expressed interest in the mice recently" and urged Würzburg to get the IIA into place "as soon as possible." [July 6, 2018 email from Mess to Zwirner-Bayer, at Ex. 13.]

107. When Würzburg pushed back against a "pre-dated" agreement that included all activities from April 14, 2005 to 2035, OSU reiterated that it "just recently became aware of the contribution the University of Wuerzurg made to the mouse model that was created in 2004 or 2005" and that "Ohio state has entered into agreements since then and [in] July 2017 would start the sharing of revenue with the University of Wuerzburg." [July 26, 2017 email from Mess to Zwirner-Bayer, at Ex. 13.]

108. Würzburg came to "understand [that] OSU made some licensing deal without knowing the University of Wurzburg was Co-owner." [July 27, 2017 email from Zwirner-Bayer to Mess, at Ex. 13.] So, the parties agreed that OSU would make a lump sum back payment of $25,000 for the period between 2005 and 2017. [*Id.*].

109. At no point did anyone from OSU inform Würzburg of the number of licenses OSU had made or the number of mice transferred to third-parties by Jackson Labs, or when. Nor did OSU disclose the full extent of its past licensing revenue, which upon information and belief, vastly exceeded the $100,000 that Würzburg believed OSU had made. OSU also did not disclose its ownership interest in AveXis.

110. The parties executed the IIA in September 2017 [*see* the Inter-Institutional Agreement, attached as Exhibit 14], purportedly to compensate Würzburg for mice that Jackson Labs distributed between 2005 and 2017 and to provide an ongoing royalty of $80,000, split between OSU, Würzburg, and Jackson Labs, for mice containing Dr. Sendtner's knockout allele.

The IIA applied only to proceeds received by OSU on or after July 1, 2017, while the $25,000 lump sum was intended to cover the period of April 14, 2005 to 2017.

111. Importantly, the IIA did not address mice containing Dr. Sendtner's knockout allele that were sold prior to 2005. Indeed, most importantly, the IIA did not address mice distributed by parties apart from Jackson Labs, including mice distributed directly by OSU.

112. At the time the IIA was negotiated and executed, Würzburg lacked material information relating to OSU's prior licensing and forthcoming commercialization. Information about OSU's prior licensing and commercial plans were in OSU's sole knowledge and possession and could not be discovered by Würzburg.

113. The information Würzburg received from OSU was false and/or materially incomplete.

114. Although Würzburg understood that OSU had entered into some licensing agreements without its knowledge between 2005 and 2017, Würzburg believed that the licensing was limited to approximately $100,000.

115. OSU never disclosed that it had breached the Agency Agreement by transferring mice to NCH, The Research Institute, and Kaspar without Würzburg's MTA.

116. OSU did not disclose that it, NCH, and The Research Institute were on the cusp of commercializing a drug developed to treat SMA using mice containing Dr. Sendtner's knockout allele, through OSU's incubator, AveXis.

117. Further, OSU did not disclose that AveXis had already received FDA approval for its IND and that clinical trials were under way.

118. Upon information and belief, throughout the months OSU and Würzburg were negotiating the IIA, AveXis was actively positioning itself for acquisition.

119. OSU did not disclose that it, NCH, and Kaspar were shareholders in AveXis. Nor did OSU disclose that AveXis was about to be purchased by Novartis.

120. Upon information and belief, OSU's reason for contacting Würzburg in late 2016 was to "clean up" loose ends prior to being acquired by Novartis.

121. Upon information and belief, OSU likely hoped that once Würzburg agreed to and accepted money under the IIA, it would not have any reason to suspect OSU, NCH, The Research Institute, or Kaspar's unauthorized actions.

122. As Würzburg's agent with respect to licensing mice containing Dr. Sendtner's knockout allele, OSU was aware that Würzburg expected 10% of all profits from any commercialization resulting from those mice.

123. OSU—still Würzburg's agent with fiduciary duties to Würzburg dating back to 2002—did not provide any of this material information. Instead, OSU stated that it had "just realized" that it shared ownership of the mice with Würzburg.

124. As Würzburg's agent, OSU was obligated to act in good faith in accordance with Würzburg's best interest and benefit and to exercise care, competence, and diligence. As Würzburg's agent, OSU was also required to disclose its ongoing efforts with third-parties to commercialize a gene therapy based on mice containing Dr. Sendtner's knockout allele and to communicate these material facts to Würzburg.

125. OSU's failure to satisfy its obligations as an agent renders the IIA voidable and/or unenforceable.

h. The IIA left intact the parties' prior Agency Agreement

126. Even if the IIA were valid and enforceable, the transfer of mice from OSU to Kaspar at The Research Institute and NCH was, by the plain terms of the IIA, outside of that

agreement. The IIA does not govern any mice distributed by OSU prior to 2005, and does not apply to mouse distributions by any party other than Jackson Labs.

127. The IIA cannot, accordingly, retroactively authorize the transfers of mice containing Dr. Sendtner's knockout allele from OSU to Kaspar, The Research Institute, and NCH.

128. Per the Agency Agreement, mice containing Dr. Sendtner's knockout allele could be distributed only by OSU after OSU had Würzburg's MTA executed by the recipient.

129. The IIA also does not disturb or displace Würzburg's and OSU's prior agreement that OSU execute Würzburg's MTA should it commercialize any research using mice containing Dr. Sendtner's knockout allele.

i. Defendants profit at Würzburg's expense

130. On April 8, 2018, AveXis entered into an agreement with Novartis to be acquired by Novartis for $8.7 billion. AveXis' drug product for SMA was AveXis' main asset and the reason for the Novartis acquisition. The acquisition was completed on May 15, 2018.

131. Kaspar received over $380 million in this acquisition.

132. NCH, The Research Institute, and OSU together owned 3% of AveXis, worth an estimated $261 million based on the Novartis stock price.

133. On May 29, 2019, Zolgensma, the AveXis drug developed using Dr. Sendtner's knockout allele, was approved by the FDA for use in the United States.

134. Zolgensma works by essentially inserting the missing SMN1 gene—the gene that Dr. Sendtner "knocked out" of the mouse—back into the genome, curing the patient of SMA. Had Dr. Sendtner never developed mice missing the SMN1 gene, this gene therapy could never have been developed.

135. The U.S. list price of Zolgensma is $2.125 million per injection and sales of Zolgensma total more than $1 billion per year.

136. Upon information and belief, OSU, NCH, and The Research Institute received and continue to receive royalties for the sale of Zolgensma.

137. Upon information and belief, OSU was also compensated under the terms of its own MTA agreement concerning use of mice containing Dr. Burghes' SMN2 insertion and Dr. Sendtner's knockout allele.

138. Würzburg, by contrast, has never been compensated for the use of mice containing Dr. Sendtner's knockout allele or for its contribution to the development of the AveXis drug now sold by Novartis.

139. Had OSU not breached the Agency Agreement, Defendants would have been subject to the 10% of Profits Clause in Würzburg's MTA.

140. Because of OSU's failures, Würzburg never received the 10% of commercialization it was entitled to under its MTA. OSU was obligated to sign that MTA itself when it realized that it would benefit from a commercial sale. OSU was also obligated to provide the MTA to NCH and The Research Institute under the Agency Agreement. It failed to do either.

141. Under Würzburg's MTA, Würzburg is entitled to 10% of the commercialization of its technology. Indeed, because Zolgensma sales are approximately $1 billion yearly, Würzburg is entitled to be compensated at 10% of $1 billion ($100 million) for each year that Zolgensma is sold.

142. To date, Würzburg has not received ***any*** compensation at all for the commercialization of Dr. Sendtner's knockout allele. Würzburg never even received the $25,000 lump sum owed to it under the IIA for licenses from 2005 to 2017.

j. OSU seeks to legitimize the IIA

143. Notwithstanding the fact that the IIA was procured by fraud and misrepresentation and is unenforceable, to this day, OSU continues to seek to enforce its terms and has attempted to pressure Würzburg into accepting payment pursuant to the unenforceable IIA.

144. On January 19, 2022, OSU contacted Würzburg to say that OSU owed it $250,000 under the IIA. On March 22, 2022, OSU again contacted Würzburg to say it was now entitled to $850,000 under the IIA.

145. Upon information and belief, OSU's recent attempts to wire Würzburg funds are OSU's last ditch and desperate attempts to compensate Würzburg for the commercialization of mice containing Dr. Sendtner's SMN knockout allele under the terms of the invalid and unenforceable IIA and to cover up its contractual and fiduciary breaches.

146. When Counsel for Würzburg asked for additional documentation to support this amount, OSU provided a spreadsheet of purported licensees under the IIA, the date of the license, the amount paid to OSU and Jackson Labs, and the dates of such payments. OSU also provided a copy of each license agreement that was executed under the IIA.

147. The documentation underlying the IIA and OSU's purported licenses reflect only OSU's attempt to create post-hoc documentation of unauthorized transfers of mice containing Dr. Sendtner's knockout allele.

148. Contrary to what OSU represented during the course of the IIA negotiations—that various companies were currently seeking a license—no licenses were entered into in 2017.

149. This documentation also showed that mice were transferred to AveXis in April 2016. Thus, for the first time, in 2022, OSU disclosed that mice were transferred to AveXis pursuant to a license with OSU.

150. Upon information and belief, OSU seeks to now compensate Würzburg for the transfer of mice to AveXis in 2016 as a way to sanitize the earlier unauthorized transfers to NCH and The Research Institute, which directly resulted in the AveXis drug product and from which all Defendants profited by several orders of magnitude above and beyond the licensing fees that OSU now seeks to share with Würzburg.

151. During the course of the IIA negotiations, OSU never disclosed to Würzburg that it had licensed mice containing Dr. Sendtner's knockout allele to AveXis, an entity in which it was a shareholder.

152. Inexplicably, OSU did not receive any compensation for this AveXis license until April 2018, March 2019, July 2020, and May 2021. For all other licenses, OSU received compensation within months of the execution of the license agreements. Because the IIA provided for profit sharing on licenses entered into and revenue received only "on or after July 1, 2017," upon information and belief, OSU delayed collection of this revenue from AveXis to ensure it fell under the terms of the revenue sharing that started in July 2017.

COUNT I
(BREACH OF CONTRACT REGARDING THE AGENCY AGREEMENT AGAINST OSU)

153. Würzburg incorporates by reference, as if fully rewritten herein, all prior allegations of this Complaint.

154. OSU entered into a valid contract with Würzburg—the Agency Agreement—and undertook to act as Würzburg's agent for the purpose of licensing and transferring mice containing Dr. Sendtner's knockout allele to ensure that Würzburg received 10% of the profits from this breakthrough.

155. OSU breached the Agency Agreement by failing to have Kaspar, NCH, and The Research Institute execute Würzburg's MTA before transferring mice containing Dr. Sendtner's knockout allele to these entities.

156. OSU also breached the Agency Agreement by failing to sign Würzburg's MTA when it engaged in the commercial use of mice containing Dr. Sendtner's knockout allele.

157. Had Kaspar, NCH, OSU, or The Research Institute executed Würzburg's MTA, they would have been obligated to provide Würzburg with 10% of the profit from the commercialization of the successful gene therapy to treat SMA, Zolgensma.

158. Würzburg reasonably relied upon OSU's representations and formed a reasonable expectation that Würzburg would receive 10% of any profits resulting from the commercialization of mice containing Dr. Sendtner's knockout allele.

159. Würzburg fully complied with the terms of the Agency Agreement—Würzburg performed all required obligations under the contract, including permitting OSU to use mice containing Dr. Sendtner's knockout allele for academic research and sending these mice to other requesting parties after those parties signed an MTA.

160. A covenant of good faith and fair dealing was implied in the Agency Agreement between Würzburg and OSU.

161. OSU breached its duty of good faith and fair dealing in the performance of the Agency Agreement by failing to provide NCH, The Research Institute, or Kaspar with an MTA

before sending them mice containing Dr. Sendtner's knockout allele. OSU also breached its duty of good faith and fair dealing under the Agency Agreement when it failed to execute Würzburg's MTA.

162. OSU further breached its duty of good faith and fair dealing in the performance of the Agency Agreement by seeking to enter into the IIA in 2017, in a further attempt to deprive Würzburg of the 10% of the profit made from the commercialization of mice containing Dr. Sendtner's knockout allele, which Würzburg expected and was entitled to.

163. OSU breached its duty of good faith and fair dealing when it offered to pay Würzburg $850,000 under the IIA, in an attempt to make the IIA enforceable and to deprive Würzburg of the 10% of profits to which it is entitled under the Agency Agreements and the MTAs.

164. OSU also breached its duty of good faith and fair dealing by providing Würzburg with all of the executed license agreements with third-parties under the IIA from 2017 to the present, including a 2016 agreement with AveXis that was solely between AveXis and OSU for the use of mice containing Dr. Sendtner's knockout allele. That agreement did not take the form of the IIA license agreements. As such, OSU improperly sought to lump this agreement in under the IIA.

165. OSU breached its duty of good faith and fair dealing by delaying collection of all license revenue under the AveXis license for years so that it could lump that license in with the IIA.

166. OSU's breaches harmed and continue to harm Würzburg.

167. Würzburg has been damaged by OSU's breach as of May 29, 2019, the date Novartis began selling Zolgensma.

168. As a direct and proximate result of OSU's breach of the Agency Agreement, Würzburg has suffered compensatory damages and consequential damages, including lost opportunity costs and/or lost profits, in an amount to be proven at trial.

COUNT II
(BREACH OF FIDUCIARY DUTY AGAINST OSU)

169. Würzburg incorporates by reference, as if fully rewritten herein, all prior allegations of this Complaint.

170. Würzburg and OSU entered into the Agency Agreement for the purposes of OSU facilitating the licensing of mice containing Dr. Sendtner's knockout allele—the Agency Agreement. Under the Agency Agreement, OSU would provide Würzburg's MTA containing the 10% of Profits Clause and ensure its execution before providing anyone with mice containing Dr. Sendtner's knockout allele.

171. Würzburg held OSU out to the public as possessing sufficient authority to license Würzburg's technology. Any third-party requesters would similarly know of OSU's authority to license on behalf of Würzburg and understood that OSU had the necessary authority to do so.

172. OSU had fiduciary duties arising out of its role as Würzburg's agent under the Agency Agreement

173. By failing to ensure that the MTA was sent to, and executed by, NCH, The Research Institute, and Kaspar before sending them mice containing Dr. Sendtner's knockout allele, OSU failed to act in good faith and with the care, competence, and diligence ordinarily exercised by agents in similar circumstances, failed to act loyally for Würzburg's benefit and in its best interests, and failed to act in accordance with Würzburg's reasonable expectations.

174. OSU similarly breached its fiduciary duties by failing to execute Würzburg's MTA, as promised, once it had commercialized an invention resulting from mice containing Dr. Sendtner's knockout allele.

175. OSU also breached its fiduciary duties to Würzburg by inducing Würzburg to execute the IIA. OSU had a large, concealed interest in AveXis, in not being subject to the 10% of Profits Clause in Würzburg's MTA, and to increase its own profit share by reducing Würzburg's. Rather than ensure that Würzburg received the compensation as defined by its MTA, OSU opted to provide Würzburg with nominal compensation and actively concealed the commercial success of a gene therapy developed directly from mice containing Dr. Sendtner's knockout allele.

176. In negotiating the IIA, OSU failed to act upon its duty to communicate to Würzburg the information it had received from AveXis, NCH, The Research Institute, and Kaspar concerning the drug product in development and the impending sale of AveXis to Novartis.

177. OSU further breached its fiduciary duties by falsely stating in 2017, when attempting to convince Würzburg to sign the IIA, that other third-parties were trying to obtain licenses. A recent accounting proves this explanation was untrue and pretextual.

178. OSU further breached its fiduciary duties to Würzburg by offering Würzburg $850,000 under the IIA in an attempt to validate the IIA and deprive Würzburg of the 10% of profits to which it is entitled.

179. OSU further breached its fiduciary duties by delaying collection of all licensing revenue under the AveXis license for years so that it could lump that license under the IIA.

180. Würzburg was damaged as a proximate result of OSU's breach of its fiduciary duties in an amount to be proved at trial.

COUNT III
(FRAUD AGAINST OSU)

181. Würzburg incorporates by reference, as if fully rewritten herein, all prior allegations of this Complaint.

182. During the negotiations leading up to the execution of the IIA, OSU failed to disclose that it had provided Kaspar, NCH, and The Research Institute with mice containing Dr. Sendtner's knockout allele.

183. OSU also failed to disclose that it had provided these mice without having Kaspar, NCH, or The Research Institute execute Würzburg's MTA.

184. OSU also failed to disclose that it itself had commercialized an invention using Dr. Sendtner's knockout allele and did so without executing Würzburg's MTA.

185. OSU also failed to disclose that a drug product for the treatment of SMA was in clinical trials, all rights in the drug had been licensed to AveXis, and AveXis was set to be acquired by Novartis for billions of dollars.

186. OSU also failed to disclose that OSU was a shareholder in AveXis, that mice containing Dr. Sendtner's knockout allele were licensed to AveXis in 2016, and that OSU had never compensated Würzburg for this license. OSU instead delayed receipt of revenue under this license and now seeks to compensate Würzburg for this AveXis license under the IIA.

187. OSU also induced Würzburg to enter into an agreement backdated to 2005, without disclosing the extent to which OSU had transferred mice containing Dr. Sendtner's knockout allele during the period from 2005 to 2017.

188. OSU also induced Würzburg to enter into the IIA by failing to disclose any licensing activity from 2002 to 2005.

189. As explanation for why it contacted Würzburg to execute an IIA, OSU also falsely stated that third-parties requested mice containing Dr. Sendtner's knockout allele. A recent accounting provided by OSU showed that this was not true.

190. OSU therefore knowingly made false statements, misrepresented facts, and concealed facts from Würzburg, and these false statements, misrepresentations, and concealed facts were material to Würzburg's decision to enter into the IIA.

191. Würzburg justifiably relied upon OSU's fraudulent misrepresentations, untruths, and omissions.

192. As a direct and proximate result of OSU's fraud, Würzburg has incurred damages in excess of $75,000.

193. OSU acted with a conscious disregard for Würzburg's rights and with a great probability of causing Würzburg substantial harm.

194. In addition to compensatory damages, because OSU acted with actual malice, Würzburg is entitled to recover punitive damages.

COUNT IV
(RESCISSION AGAINST OSU)

195. Würzburg incorporates by reference, as if fully rewritten herein, all prior allegations of this Complaint.

196. In the event that the IIA is deemed valid and in existence between Würzburg and OSU, Würzburg rescinds the IIA due to OSU's fraudulent misrepresentations and/or omissions.

197. By signing the IIA, OSU expressly or impliedly represented it would comply with the terms of the IIA.

198. OSU knew that those representations were false when it made them.

199. OSU made those representations with an intent to mislead Würzburg to rely on those representations.

200. OSU had a duty to inform Würzburg that it was not complying with the terms of the IIA.

201. Würzburg relied on OSU's false representations, had a right to rely on them, and incurred injury as a direct and proximate result of its reliance.

COUNT V
(UNJUST ENRICHMENT AGAINST OSU, KASPAR, NCH, AND THE RESEARCH INSTITUTE)

202. Würzburg incorporates by reference, as if fully rewritten herein, all prior allegations of this Complaint.

203. Würzburg conferred a benefit upon Defendants by providing the scientific innovation that Dr. Sendtner's knockout allele represented on the road to develop a treatment for SMA.

204. Defendants had knowledge of the scientific innovation that Dr. Sendtner's knockout allele represented and that the mice containing this knockout allele were an important milestone in the road to develop a treatment for SMA. Defendants had knowledge that they each benefited from Würzburg's technology.

205. OSU received the benefit of mice containing Dr. Sendtner's knockout allele and used these mice to develop further research and knowledge towards a treatment for SMA. Evidence of this benefit is reflected in the compensation OSU received from licensing its technology to NCH and The Research Institute, the considerable purchase price Novartis paid to AveXis, OSU's ongoing royalties for sales of Zolgensma, as well as any compensation OSU

received under the terms of its own MTA agreements whenever OSU licensed mice to other institutions.

206. NCH and The Research Institute received the benefit of mice containing Dr. Sendtner's knockout allele and used these mice to develop further research and knowledge towards a treatment for SMA. Evidence of this benefit is reflected in the compensation NCH and The Research Institute received when they licensed technology to AveXis, the considerable purchase price Novartis paid to AveXis, and their ongoing royalties for sales of Zolgensma.

207. Kaspar received the benefit of mice containing Dr. Sendtner's knockout allele and used these mice to develop further research and knowledge towards a treatment for SMA. Evidence of this benefit is reflected in the more than $380 million valuation of the stock Kaspar held when AveXis was acquired by Novartis.

208. Defendants would not have obtained such benefits without the unauthorized use of mice containing Dr. Sendtner's knockout allele.

209. Defendants have each knowingly retained the benefit of Dr. Sendtner's technology without compensating Würzburg.

210. It would be inequitable for Defendants to retain the benefits received at the expense of Würzburg without compensation to Würzburg, and therefore this Court should order an equitable remedy or award damages to remedy this unjust enrichment.

COUNT VI
(TORTIOUS INTERFERENCE WITH A CONTRACT AGAINST KASPAR, NCH, AND THE RESEARCH INSTITUTE)

211. Würzburg incorporates by reference, as if fully rewritten herein, all prior allegations of this Complaint.

212. OSU and Würzburg had a business relationship and were parties to the Agency Agreement, under which OSU served as Würzburg's agent for the purposes of licensing hybrid mice containing Dr. Sendtner's knockout allele.

213. NCH, The Research Institute, and Kaspar had knowledge both of OSU's and Würzburg's business relationship, Würzburg's MTAs, Würzburg's requirement that it receive 10% of profits, and the Agency Agreement between OSU and Würzburg.

214. Nonetheless, Kaspar, NCH, and The Research Institute used mice containing Dr. Sendtner's knockout allele in furtherance of their own academic research and eventually for commercial purposes, without ever signing Würzburg's MTA.

215. Kaspar, NCH, and The Research Institute did not compensate Würzburg after they commercialized a drug product that was developed using mice containing Dr. Sendtner's knockout allele. Nor did the Defendants compensate Würzburg following the sale of AveXis to Novartis or the sales of Zolgensma.

216. By neither signing Würzburg's MTA nor compensating Würzburg with 10% of their profits, Kaspar, NCH, and The Research Institute facilitated the breach of the Agency Agreement by OSU.

217. Kaspar, NCH, and The Research Institute's intentional and improper use of, and financial gain from, mice containing Dr. Sendtner's knockout allele was the cause of OSU's breach of the relationship between OSU and Würzburg.

218. Kaspar, NCH, and The Research Institute's intentional and improper use of, and financial gain from, mice containing Dr. Sendtner's knockout allele was the cause of the breach of the Agency Agreement between OSU and Würzburg.

219. OSU was rewarded for its breach of the Agency Agreement as it was given an ownership interest in AveXis.

220. Würzburg has been damaged as a result of Kaspar, NCH, and The Research Institute's tortious interference with Würzburg and OSU's business relationship and the Agency Agreement.

COUNT VII
(CIVIL CONSPIRACY AGAINST OSU, KASPAR, NCH, AND THE RESEARCH INSTITUTE)

221. Würzburg incorporates by reference, as if fully rewritten herein, all prior allegations of this Complaint.

222. Upon information and belief, OSU, Kaspar, NCH, and The Research Institute participated in a malicious combination involving two or more persons, a result of which was the commission of a wrongful or unlawful act that caused damages to other parties.

223. In particular, OSU agreed to act as Würzburg's agent for the purposes of ensuring that mice containing Dr. Sendtner's knockout allele were licensed pursuant to Würzburg's MTA. OSU committed not to distribute such mice without an MTA. Dr. Burghes and the Tech Transfer Office at OSU were aware of Würzburg's MTA, OSU's obligations with respect to this MTA, and Würzburg's expectation that Würzburg would receive 10% of profits from any commercial use of mice containing Dr. Sendtner's knockout allele.

224. Kaspar, The Research Institute, and NCH were also aware of Dr. Sendtner's knockout allele, Würzburg's MTA, and Würzburg's expectation that Würzburg would receive 10% of profits from any commercial use of mice containing Dr. Sendtner's knockout allele.

225. OSU permitted Kaspar, The Research Institute, and NCH to nonetheless use mice containing Dr. Sendtner's knockout allele, without executing Würzburg's MTA, to develop and

commercialize a gene therapy. Kaspar, The Research Institute, and NCH never shared any of the profits from such commercial use, thereby causing actual damages to Würzburg.

226. OSU commercialized mice containing Dr. Sendtner's knockout allele, but it never signed Würzburg's MTA, despite its contractual obligation to do so. OSU licensed inventions based on mice containing Dr. Sendtner's knockout allele to NCH and The Research Institute and conspired with NCH and The Research Institute to deprive Würzburg of money to which it would have otherwise been entitled.

227. By accepting mice containing Dr. Sendtner's knockout allele from OSU, knowing Würzburg expected its MTA to be executed and to receive 10% of profits from commercialization, Kaspar, NCH, and The Research Institute conspired with OSU to deprive Würzburg of money to which it would have otherwise been entitled.

228. By accepting millions of dollars from the use of mice containing Dr. Sendtner's SMN knockout allele, Kaspar, NCH, and The Research Institute conspired with OSU to deprive Würzburg of money to which it would have otherwise been entitled.

229. Defendants conspired to keep these facts from Würzburg.

230. As a direct and proximate result of the conspiracy committed by Defendants, Würzburg has incurred damages, including attorneys' fees and costs.

COUNT VIII
(DECLARATORY JUDGMENT AGAINST OSU, NCH, THE RESEARCH INSTITUTE, AND KASPAR)

231. Würzburg incorporates by reference, as if fully rewritten herein, all prior allegations of this Complaint.

232. A justiciable controversy exists between Würzburg and Defendants regarding Defendants' obligations to reimburse Würzburg for Würzburg's and Dr. Sendtner's research and innovations that resulted in the creation of a new treatment for SMA.

233. Würzburg has a legal interest in this controversy.

234. Under 28 U.S.C. § 2201(a) and Ohio Revised Code § 2721.02, Würzburg prays for a declaration from this Court holding that Defendants are obligated to reimburse Würzburg for Würzburg's and Dr. Sendtner's research and innovations that resulted in the creation of a new treatment for SMA, including but not limited to a declaration that Würzburg is due royalties from all sales of Zolgensma.

PRAYER FOR RELIEF

WHEREFORE, Würzburg respectfully requests that a judgment be granted in its favor:

A. Awarding Würzburg damages in excess of $75,000, including compensatory damages, as well as attorneys' fees, prejudgment and post judgment interest at the statutory rate, punitive damages, costs, expenses, and all other damages against Defendants that the Court deems just and appropriate;

B. Enter a declaratory judgment that Würzburg is due royalties from all sales of Zolgensma; and

C. For any other legal or equitable relief to which Würzburg is entitled and this Court deems appropriate.

JURY DEMAND

The University of Würzburg demands a trial by jury of the maximum number of jurors allowed, on all issues so triable.

Respectfully submitted,

/s/ Justin M. Croniser

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